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APPLICATION NO. FILING DATE FIRST NAMED INVENTOR ATTORNEY DOCKET NO. CONFIRMATION NO. 08/716,344 11/26/1996 ROLF ENGSTAD CU-1446TJK 5681 7590 02/09/2004 EXAMINER JOHN J CHRYSTAL PRATS, FRANCISCO CHANDLER LADAS & PARRY 224 SOUTH MICHIGAN AVENUE ART UNIT PAPER NUMBER CHICAGO, IL 60604 1651 .

DATE MAILED: 02/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

		Application N .	Applicant(s)
	Office Action Summary	08/716,344	ENGSTAD ET AL.
•		Examiner	Art Unit
	The MAILING DATE of this	Francisco C Prats	1651
	The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply		
	A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any		
	Status	•	, coood uny
	1) Responsive to communication(s) filed on 13 January 2004.  2a) This action is FINAL. 2b) This action is non-final.  3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.  Disposition of Claims  4) Claim(s) 1-21 is/are pending in the application.  4a) Of the above claim(s) is/are withdrawn from consideration.  5) Claim(s) is/are allowed.  6) Claim(s) 1-21 is/are rejected.  7) Claim(s) is/are objected to.		
8) Claim(s) are subject to restriction and/or election requirement.  Application Papers			
	<ul> <li>9) The specification is objected to by the Examiner.</li> <li>10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner.  Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).</li> <li>11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.</li> </ul>		
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P	riority under 35 U.S.C. § 119		
	12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  a) All b) Some * c) None of:		
	1. Certified copies of the priority documents have been received.		
	2. Certified copies of the priority documents have been received in Application No.  3. Copies of the certified copies of the priority documents have been received in this National Stage		
The international Bureau (PC: [.Rule 17 2/a))			Tuns National Stage
	* See the attached detailed Office action for a list of the certified copies not received.		
	*		
Atta	achment(s)		
1) [	Notice of References Cited (PTO_802)		
2) L	☐ Notice of Draftsperson's Patent Drawing Position (DTC 0.40)	4) Interview Summary (PTC	)-413)
0,2	Paper No(s)/Mail Date <u>1-13-04</u> .	Paper No(s)/Mail Date 5) Notice of Informal Patent 6) Other:	Application (PTO-152)
U.S. Pa	tent and Trademark Office		

Art Unit: 1651

#### DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on January 13, 2004, has been entered.

The amendment to the claims filed on January 13, 2004, does not comply with the requirements of 37 CFR 1.121(c) because it does not contain a listing of all claims in the case along with a status identifier as a parenthetical expression. Amendments to the claims filed on or after July 30, 2003 must comply with 37 CFR 1.121(c) which states:

(c) Claims. Amendments to a claim must be made by rewriting the entire claim with all changes (e.g., additions and deletions) as indicated in this subsection, except when the claim is being canceled. Each amendment document that includes a change to an existing claim, cancellation of an existing claim or addition of a new claim, must include a complete listing of all claims ever presented, including the text of all pending and withdrawn claims, in the application. The claim listing, including the text of the claims, in the amendment document will serve to replace all prior versions of the claims, in the application. In the claim listing, the status of every claim must be indicated after its claim number by using one of the following identifiers in a parenthetical expression: (Original),

Art Unit: 1651

Page 3

(Currently amended), (Canceled), (Withdrawn), (Previously presented), (New), and (Not entered).

- (1) Claim listing. All of the claims presented in a claim listing shall be presented in ascending numerical order. Consecutive claims having the same status of "canceled" or "not entered" may be aggregated into one statement (e.g., Claims 1-5 (canceled)). The claim listing shall commence on a separate sheet of the amendment document and the sheet(s) that contain the text of any part of the claims shall not contain any other part of the amendment.
- (2) When claim text with markings is required. All claims being currently amended in an amendment paper shall be presented in the claim listing, indicate a status of "currently amended," and be submitted with markings to indicate the changes that have been made relative to the immediate prior version of the claims. The text of any added subject matter must be shown by underlining the added text. The text of any deleted matter must be shown by strike-through except that double brackets placed before and after the deleted characters may be used to show deletion of five or fewer consecutive characters. The text of any deleted subject matter must be shown by being placed within double brackets if strike-through cannot be easily perceived. Only claims having the status of "currently amended," or "withdrawn" if also being amended, shall include markings. If a withdrawn claim is currently amended, its status in the claim listing may be identified as "withdrawn-currently amended."
- (3) When claim text in clean version is required. The text of all pending claims not being currently amended shall be presented in the claim listing in clean version, i.e., without any markings in the presentation of text. The presentation of a clean version of any claim having the status of "original," "withdrawn" or "previously presented" will constitute an assertion that it has not been changed relative to the immediate prior version, except to omit markings that may have been present in the immediate prior version of the claims of the status of "withdrawn" or "previously presented." Any claim added by amendment must be indicated with the status of "new" and presented in clean version, i.e., without any underlining.
- (4) When claim text shall not be presented; canceling a claim.
- (i) No claim text shall be presented for any claim in the claim listing with the status of "canceled" or "not entered."
- (ii) Cancellation of a claim shall be effected by an instruction to cancel a particular claim number. Identifying

Art Unit: 1651

the status of a claim in the claim listing as "canceled" will constitute an instruction to cancel the claim.

(5) Reinstatement of previously canceled claim. A claim which was previously canceled may be reinstated only by adding the claim as a "new" claim with a new claim number.

Technically, applicant's inadvertent failure to adhere to Rule 121 constitutes a non-responsive amendment. Should applicant again fail to submit an amendment in improper form, the amendment will be held non-responsive. However, in the interest of compact prosecution, the claims will be examined.

Claims 1-21 are pending and are examined on the merits.

# Claim Rejections - 35 USC § 112

Claims 20 and 21 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Specifically, the new language in claim 20 requiring "four or less  $\beta$ -1,6-bound glucose units" lacks support in the specification as filed. Note that the new matter rejection over

Art Unit: 1651

the language "essentially free" has been withdrawn in view of the literal support present in the specification on page 4, lines 9-16, as argued by applicant.

However, the new language in claim 20 requires the glucan molecule to have no more than four  $\beta$ -1,6-bound glucose units. This is not what is described in the specification. Rather, page 4, lines 9-16, of the specification describe a molecule wherein either most or essentially all of the short  $\beta$ -1,6-linked branches of 4 glucose units or fewer have been removed. That is, depending on what "essentially" means, the described product will basically have no side chains of 4 or fewer glucose units. However, the molecule described in the specification has no limit as to the number of  $\beta$ -1,6-linked branches of more than 4 glucose units. Thus, the new limitation in claim 20 requiring "four or less  $\beta$ -1,6-bound glucose units" lacks support in the specification as filed. This is a new matter rejection.

Claims 1-21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The recitation "essentially free" (claims 1, 7, 8, 9, 13, 16, 21 and 22) is indefinite because it is not clear what

Art Unit: 1651

percentage of β-1,6-linked chains must be eliminated for a particular glucan to be considered essentially free of such chains. One of skill in the art would reasonably construe "essentially free" to mean none, or so few that detection would be unlikely. However, the specification, at page 4, lines 9-16, states that the enzymatic removal process only removes "most" of the undesired side chains. Thus, the same paragraph providing literal support for the terminology "essentially free" requires only that "most" of the undesired side chains were removed.

Because "most" can be taken to mean "greater than 50%", and because "greater than 50%" has a vastly different meaning than "essentially free", the metes and bounds of the claim language are simply not clear. Because of applicant's inconsistent use of the term "essentially free", a holding of indefiniteness is clearly required.

All of applicant's argument regarding this ground of rejection has been fully considered but is not persuasive of error. The new matter rejection set forth in the previous office action has been withdrawn in view of the literal support in the specification for the terminology "essentially free." However, as discussed above, the same paragraph on page 4 of the specification provides inconsistent meanings with respect to what the metes and bounds of this term are. Because the claims

Art Unit: 1651

fail to clearly delineate the claimed subject matter, the rejection must be maintained.

### Claim Rejections - 35 USC § 102.

Claims 1, 4, 5, 7, 9, 10, 13, 14 and 16-19 are rejected under 35 U.S.C. 102(b) as being anticipated by Shiota et al (J. Biochem. 98:1301-1307 (1985)).

Shiota et al disclose a process wherein the claimdesignated polysaccharide, Saccharomyces cerevisiae  $\beta$ -glucan, is hydrolyzed with the claim-designated enzyme. See p. 1303. ("Enzymatic hydrolysis of the skeletal glucan was performed with . . . Neurospora crassa endo- $(\beta$ -1-6)-glucanase. The sample (about 100 mg) was incubated with . . . the endo- $(\beta$ -1-6)-glucanase (2.8 U) in 2 ml of sodium acetate buffer (0.01 M, pH 5.0) at 35 C for 24 h.").

It is noted that the claims have been amended to require the glucan to be in insoluble particulate form, and that the glucans are essentially free of  $\beta$ -1,6-linked chains of 4 or less glucose chains. As an aside note that applicant's marked-up copy of claims 1 and 7 failed to indicate that the term "particulate" was newly inserted at line 2 of each of those claims. Regardless, the limitation requiring insoluble particles is considered to be met by Shiota based on the fact

Art Unit: 1651

that the glucan prepared by Shiota is the insoluble fraction obtained by alkali and acid extraction. See page 1302, right hand column, paragraph entitled "Preparation of Cell Wall Skeletal Glucan." Note specifically that this is a virtually identical process by which the glucan starting material is prepared in Example 1 of applicant's specification.

Similarly, Shiota meets the new limitation requiring the glucans to be essentially free of  $\beta$ -1,6-linked chains of 4 or less glucose chains because Shiota contacts the identical material as claimed with an enzyme having an identical catalytic activity. By subjecting the same material as claimed to the same conditions, the result must necessarily be the same. The laws of chemistry require it. Thus Shiota anticipates the claimed processes and products.

All of applicant's argument regarding this ground of rejection has been fully considered but is not persuasive of error. Applicant initially argues that the glucanase used by Shiota is from a different microorganism than the claimed glucanase. However, it is respectfully pointed out that none of the claims in this ground of rejection recite anything about the source microorganism for the enzyme. Thus, applicant is arguing about a limitation not present in the claims.

Application/Control Number: 08/716,344 Art Unit: 1651

Applicant's assertion that the claimed glucan product is different from Shiota's glucan product is not based on any fact in evidence. Rather, applicant states that the products are different, without offering any evidentiary support whatsoever for that statement. Shiota contacts a starting material identical to the claimed starting material with an enzyme having a catalytic activity identical to the claimed enzyme. The inevitable result is that the resulting product will be the same.

Moreover, to the extent that applicant urges that Shiota's product is not essentially free of  $\beta$ -1,6-linked chains of 4 or less glucose units, applicant provides no direct evidence in support of this assertion. Further still, in view of the fact that the specification requires removal of only "most" of the undesired side chains to have a glucan "essentially free" of undesired side chains, applicant's argument ignores the relatively broad scope of the claims. In sum, because applicant has failed to provide any evidence that the products are different, the rejection must be maintained.

Claims 1, 2, 4, 5, 7, 9, 10, 13, 14 and 16-19 are rejected under 35 U.S.C. 102(b) as being anticipated by Yamamoto et al (Agr. Biol. Chem. 38(8):1493-1500 (1974)).

Art Unit: 1651

Yamamoto discloses a process wherein yeast glucan (the claimed starting material) is contacted with an endo- $\beta$ -1,6-glucanase (the claimed enzyme) from *Rhizopus chinensis* (one of the claimed microorganism sources for the enzyme). See, e.g., page 1497, Table IV; see also Fig 11. Note specifically that the hydrolysis was performed for 45 hours, until an apparent steady state was reached. Therefore, the reference is properly considered to describe removal of essentially all  $\beta$ -1,6-linked side chains. A holding of anticipation over the cited claims is required.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 20 and 21 are rejected under 35 U.S.C. 102(e) as being anticipated by Rorstad et al (U.S. Pat. 5,401,727).

Rorstad discloses the immunostimulation of fish by intraperitoneal injection of glucans. See, e.g., columns 7 and

Application/Control Number: 08/716,344 Art Unit: 1651

8. It is noted that, unlike claims 20 and 21, the preferred glucan for immunostimulation in Rorstad is a highly branched product called M-glucan. See, e.g., column 5, lines 1-11. However, Rorstad broadly discloses that the glucans decribed therein include unbranched glucans (column 4, lines 48-52), as well as molecules having "at least one branch of glucopyranose units linked by beta-1,6 bonds" (column 4, lines 55-56). Thus, glucans suitable for use in Rorstad's immunostimulation process can be unbranched or contain as few as one  $\beta$ -1,6-linked side chain. Rorstad's immunostimulatory glucans can therefore be considered to be "essentially free" of such side chains. Therefore, despite the fact that Rorstad describes a different glucan than recited in claims 20 and 21 as being the preferred glucan for immunostimulation in fish, a holding of anticipation is clearly required. See MPEP § 2123.

# Claim Rejections - 35 USC § 103

Claims 1-3 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shiota et al (J. Biochem. 98:1301-1307 (1985)) or Yamamoto et al (Agr. Biol. Chem. 38(8):1493-1500 (1974)) in view of de la Cruz et al (Arch. Microbiol. 159:316-322 (1993)).

Claims 2 and 3 limit the  $\beta$ -1,6-glucanase of claim 1 to an enzyme obtained from  $Trichoderma\ harzianum$ . As discussed

Art Unit: 1651

immediately above, both Shiota and Yamamoto anticipate claim 1. However, the  $\beta$ -1,6-glucanase used by Shiota and Yamamoto is from a different microorganism than the  $\beta$ -1,6-glucanase recited in claim 3. Despite this difference, the artisan of ordinary skill at the time of applicant's invention would have recognized and reasonably expected that any  $\beta$ -1,6-glucanase, including the  $\beta$ -1,6-glucanase disclosed by de la Cruz, could have been used equivalently to the  $\beta$ -1,6-glucanase used in the Shiota process. Thus, because the process recited in claims 2 and 3 differs from Shiota only in the use of a known equivalent  $\beta$ -1,6-glucanase enzyme, the process recited in claims 2 and 3 would have been obvious at the time of applicant's invention.

All of applicant's argument regarding this ground of rejection has been fully considered but is not persuasive of error. Applicant again asserts that the claimed combination of references cannot render the claimed subject matter obvious because the claimed product is different from that disclosed by Shiota et al. However, as discussed above, applicant has provided no evidence in support of this assertion. On the current record it is clear that the same starting material as claimed, yeast glucan, is contacted with an enzyme having the same catalytic activity as claimed, endo- $\beta$ -1,6-glucanase activity. Thus, if there is a difference between Shiota's

Art Unit: 1651

product and the claimed product, it is due to some unclaimed aspect of the invention. Moreover, because one of ordinary skill would have considered enzymes having endo- $\beta$ -1,6-glucanase activity to be interchangeably equivalent, regardless of source microorganism, the artisan of ordinary skill would have considered obvious the claimed substitution of de la Cruz's enzyme for Shiota's enzyme. That is, in view of Shiota's disclosure of the requirement for endo- $\beta$ -1,6-glucanase activity, the artisan of ordinary skill would have considered the use of such an enzyme obvious, regardless of source microorganism. The rejection must be maintained.

Claims 1, 6 and 13-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shiota et al (J. Biochem. 98:1301-1307 (1985)) in view of Jamas (U.S. Pat. 5,028,703).

Claims 6 and 15 limit the processes of claims 1 and 13 to processes wherein specific extraction steps are performed. As discussed above, Shiota anticipates claims 1, 13 and 14.

However, Shiota does not disclose processes wherein the exact process steps recited in claims 6 and 15 are performed. Despite this difference, Jamas discloses that, prior to acid or enzymatic treatment, glucan derived from Saccharomyces cerevisiae can be extracted from yeast using a variety of

Art Unit: 1651

extraction techniques under a variety of conditions, including those employed in the process recited in claims 6 and 15. See e.g. Jamas at col. 6, lines 3-6. ("The digested glucan particles can be, if necessary, subjected to further washings and extraction to reduce the protein and contaminant level to the preferred amounts hereinbefore indicated.") Moreover, the claimed repetition of extraction steps is disclosed by Shiota, which discloses numerous repetitions of the extraction steps.

Thus, while the exact sequence of process steps recited in claims 6 and 15 are not disclosed by either Shiota or Jamas, both of the references disclose that the claimed steps were conventional in the art at the time of applicant's invention. Thus, the artisan of ordinary skill at the time of applicant's invention would have deemed the process recited in claims 6 and 15 obvious over the cited references, the claimed process being an optimization of the processes disclosed by Shiota and Jamas, using conventional extraction steps disclosed by those references.

All of applicant's argument regarding this ground of rejection has been fully considered but is not persuasive of error. Applicant again asserts that the claimed combination of references cannot render the claimed subject matter obvious because the claimed product is different from that disclosed by

Application/Control Number: 08/716,344 Art Unit: 1651

Shiota et al. However, as discussed above, applicant has provided no evidence in support of this assertion. On the current record it is clear that the same starting material as claimed, yeast glucan, is contacted with an enzyme having the same catalytic activity as claimed, endo- $\beta$ -1,6-glucanase activity. Thus, if there is a difference between Shiota's product and the claimed product, it is due to some unclaimed aspect of the invention. The rejection must therefore be maintained.

Claims 10 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shiota et al (J. Biochem. 98:1301-1307 (1985)) in view of Jamas (U.S. Pat. 5,028,703), and in further view of Matsueda et al (GB 2 076 418).

Claim 11 limits the process of claim 10 to one in which formic acid is employed as the acid solubilizing agent. As discussed above, Shiota anticipates claim 10. However, Shiota does not disclose processes wherein formic acid is employed as the acid solubilizing agent. Rather, Shiota employs acetic acid as the solubilizing agent. Despite this difference, Jamas, which also discloses the use of acetic acid as a glucan solubilizing agent, also discloses that other acids may be employed as solubilizing agents. See Jamas at col. 6, line 67,

Art Unit: 1651

through col. 7, line 3. ("Acetic acid is preferred, due to its mild acidity, ease of handling, low toxicity, low cost and availability, but other acids may be used. Generally these acids should be mild enough to limit hydrolysis of the  $\beta(1-3)$  linkages.") Further still, Matsueda discloses that formic acid can be used as a pre-enzymatic hydrolysis solubilizing agent for an anti-tumor glucan having a  $\beta$ -1,3 glucan backbone and  $\beta$ -1,6 branch structures.

Thus, the artisan of ordinary skill at the time of applicant's invention would have deemed obvious the substitution of the formic acid of Matsueda for the acetic acid used in the Shiota process. The artisan of ordinary skill would have recognized from the Jamas disclosure that acids mild enough to preserve the  $\beta$ -1,3 glucan backbone could have been used equivalently to the acetic acid used in the Shiota process, and would further have recognized from the Matsueda disclosure that formic acid is such an acid. Thus, the artisan of ordinary skill at the time of applicant's invention would have considered the use of formic acid recited in claim 11 to have been the substitution of one art-recognized equivalent for another, and therefore obvious under § 103.

All of applicant's argument regarding this ground of rejection has been fully considered but is not persuasive of

Art Unit: 1651

error. While applicant urges that the claimed enzymatic treatment does not solubilize the yeast glucans, it is respectfully pointed out that Shiota's process also results in an insoluble product. See page 1303, left hand column, disclosing that the enzyme-hydrolyzed "precipitate was washed with water and lyophilized", thus clearly disclosing the recovery of an insoluble product. Thus, the insoluble particulate product recited in claims other than claims 10 and 11 is clearly disclosed by Shiota.

Relevant to claims 10 and 11, notably, the soluble supernatant was also recovered. See page 1303. ("The resulting supernatant was applied to a Bio-Gel P-2 column (1.5 x 150 cm and eluted with water.") Moreover, the product was recovered after combined treatment with enzyme and a pH 5.0 environment. See page 1303 first paragraph, left column. Claims 10 and 11 do not recite any specific amount of solubilizing agent. Thus claims 10 and 11 encompass the use of acid solubilizing agent in an amount which would result in pH 5.0, as disclosed in Shiota. Lastly, in view of Jamas' and Matsueda's clear disclosure of the desirability of solubilizing glucan with formic acid, the artisan of ordinary skill clearly would have been motivated to have used formic acid to have solubilized the glucan of Shiota. In sum, while applicant argues a difference between the claims

Art Unit: 1651

and the prior art, the claims are sufficiently broad so as to encompass processes suggested by the prior art. The rejection must therefore be maintained.

# Claim Rejections - 35 USC § 102/103

Claims 8 and 12 are rejected under 35 U.S.C. § 102(b) as anticipated by or, in the alternative, under 35 U.S.C. § 103 as obvious over Shiota et al (J. Biochem. 98:1301-1307 (1985)).

Shiota et al disclose a glucan product which appears to be identical to the presently claimed glucan product because the product results from contacting the claimed starting material, Saccharomyces cerevisiae glucan, with the claimed enzyme,  $\beta$ -1,6 glucanase. Consequently, the claimed product appears to be anticipated by the reference.

While it appears that the prior art product and the claimed product must necessarily be identical, it is noted that the prior art and claimed products are prepared by processes which differ somewhat in their initial extraction steps. However, even if the reference glucan and the claimed glucan are not one and the same and there is, in fact, no anticipation, the reference glucan would, nevertheless, have rendered the claimed glucan obvious to one of ordinary skill in the art at the time the claimed invention was made in view of the clearly close

Art Unit: 1651

relationship between the products as evidenced by the fact that they are prepared from the same starting material, and are therefore structurally very closely related compounds.

Thus the claimed invention as a whole was clearly prima facie obvious especially in the absence of sufficient, clear, and convincing evidence to the contrary.

Regarding propriety of an alternative rejection, note that MPEP § 706.3(e) states that:

"[w]hen the prior art discloses a product which reasonably appears to be either identical with or only slightly different than a product claimed in a product-by-process claim, a rejection based alternatively on either section 35 U.S.C. 102 or 35 U.S.C. 103 of the statute is appropriate. As a practical matter, the Patent and Trademark Office is not equipped to manufacture products by the myriad of processes put before it and then obtain prior art products and make physical comparisons therewith. A lesser burden of proof is required to make out a case of prima facie obviousness for product-by-process claims because of their peculiar nature than when a product is claimed in the conventional fashion. In re Brown, 59 CCPA 1063, 173 USPQ 685 (1972); In re Fessmann, 180 USPQ 324 (CCPA1974)."

All of applicant's argument regarding this ground of rejection has been fully considered but is not persuasive of error. As discussed above, applicant has not supported the assertion that the product of Shiota is different than the claimed product by any evidence of record. It is again pointed out that on the current record it is clear that Shiota contacts a starting material identical to the claimed starting material

Art Unit: 1651

with an enzyme having a catalytic activity identical to the claimed enzyme. The inevitable result is that the resulting product will be the same. If there is some difference between the products, the difference must be due to some unclaimed aspect of the invention. Again, applicant asserts that a difference between the prior art product and the claimed product exists, but applicant does not state what that difference is, nor does applicant actually demonstrate a difference using actual facts. The rejection must therefore be maintained

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Francisco C Prats whose telephone number is 571-272-0921. The examiner can normally be reached on Monday through Friday, with alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Art Unit: 1651

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Francisco C Prats Primary Examiner Art Unit 1651

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